NOV 22 2000

Allegiance
a Cardinal Health company

K003370

Allegiance Healthcare Corporation
1500 Waukegan Road
847.473.1500
FAX: 847.785.2460
McGaw Park, Illinois 60085 USA

17. SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
JAMSHIDI® MARROW ACQUISITION CRADLE BIOPSY NEEDLE

Manufacturer:	Allegiance Healthcare Corporation 400 East Foster Road Mannford, OK 74044
Regulatory Affairs Contact:	Lavenia Ford 1500 Waukegan Road MPK McGaw Park, IL 60085
Telephone:	(847) 785-3323
Date Summary Prepared:	10/3/2000
Common Name:	Jamshidi® Marrow Acquisition Biopsy Needle
Classification:	Class II per 21CFR § 876.1075
Predicate Device:	Allegiance Jamshidi® Bone Marrow Biopsy Needle
Description:	Jamshidi® Marrow Acquisition Cradle is a device that works in conjunction with the Jamshidi® Bone Marrow/Aspiration Needle. It is comprised of a biopsy ejector/support probe and cutting retention cannula that is inserted into the bone marrow needle for ease of bone marrow sample removal.

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17. SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
JAMSHIDI® MARROW ACQUISITION CRADLE BIOPSY NEEDLE

Intended Use:

The Marrow Acquisition Cradle is a device intended to be placed inside of the bone biopsy needle cannula to mechanically cut bone marrow. The bone marrow specimen is contained within the cradle during withdrawal from the cannula. The biopsy ejector/support probe is used to remove the core sample from within the cradle. The intended use of the device is to obtain a core bone marrow tissue sample for diagnostic analysis.

Substantial Equivalence:

The Jamdhidi Marrow Acquisition Cradle is substantially equivalent to the Jamshidi Bone Marrow Biopsy/Aspiration/Needle in that:

- the intended use is the same
- the performance attributes are the same

Summary of Testing:

All material used in the fabrication of this Jamshidi® Marrow Acquisition Cradle were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were USP Class VI, Muscle Implant, Acute Systemic Toxicity, Intracutaneous Toxicity as required. These materials have met the requirements of the guidance and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Ms. Lavenia Ford
Regulatory Affairs Manager
Allegiance Healthcare Corporation
1500 Waukegan Road
Building WM
McGaw Park, Illinois 60085

Re: K003370
Trade Name: Jamshidi® Marrow Acquisition Cradle
Regulatory Class: II
Product Code: KNW
Dated: October 3, 2000
Received: October 30, 2000

Dear Ms. Ford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance
a Cardinal Health company

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
Fax: 847.785.2461

510(k) Number (if known): K003370 Unknown

Device Name: Jamshidi®Marrow Acquisition Cradle

Indications For Use: The Marrow Acquisition Cradle is a device intended to be placed inside of the bone biopsy needle cannula to mechanically cut bone marrow. The bone marrow specimen is contained within the cradle during withdrawal from the cannula. The biopsy ejector/support probe is used to remove the core sample from within the cradle. The intended use of the device is to obtain a core bone marrow tissue sample for diagnostic analysis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The Counter Use ____
(Per 21 CFR 801.109)

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for Mark N. Melkerson
(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003370